Notice of Allowability	Application No.	Applicant(s)	
	09/843,819	NAKAYAMA ET AL.	
	Examiner	Art Unit	
	Sally A. Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *1/25/2005*.

2. ☒ The allowed claim(s) is/are *1,3-11 and 13-22*.

3. ☒ The drawings filed on *30 April 2001* are accepted by the Examiner.

4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☒ None of the:
   1. ☒ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
   1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date *5/12/2005*. 5/12/2005
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. Please amend the claims as follows:

Amend claim 1 as follows:

1. A method for synthesis of nucleic acids which comprises: adding a [living body] sample comprising a cell, fungus, bacterium, or virus to an amplification reaction solution comprising a polyhydric alcohol and ammonium sulfate, wherein said cell, fungus, bacterium, or virus of said [living body] sample is intact and unlysed without extracting and/or purifying said nucleic acid from inside said cell, fungus, bacterium, or virus, when said [living body] sample is added to the amplification reaction solution, and

directly amplifying said nucleic acid from said intact and unlysed cell, fungus, bacterium, or virus in said amplification reaction solution, said amplification being in a region rich in guanine (G) and cytosine (C) content,

wherein said amplifying step consists of (i) preheating said amplification reaction solution, (ii) denaturing said nucleic acid, (iii) annealing a primer to said denatured nucleic acid, and (iv) polymerizing said primer, and

wherein said steps(ii), (iii), and (iv) of said amplifiying step are repeated.

Amend claim 13 as follows:

13. A method for synthesis of nucleic acids, which comprises:

adding a cell fungus, bacterium, or virus to an amplification reaction solution comprising a polyhydric alcohol and ammonium sulfate, wherein said cell, fungus, bacterium, or virus is added to the amplification reaction solution intact and unlysed without extracting and/or purifying said nucleic acid from inside said cell, fungus, bacterium, or virus, and

directly amplifying said nucleic acid from said intact and unlysed cell, fungus, bacterium, or virus in said amplification reaction solution, said amplification being in a region rich in guanine (G) and cytosine (C) content,

wherein said amplifying step consists of (i) preheating said amplification reaction solution, (ii) denaturing said nucleic acid, (iii) annealing a primer to said denatured nucleic acid, and (iv) polymerizing said primer, and

wherein said steps(ii), (iii), and (iv) of said amplifiying step are repeated.

THE FOLLOWING IS AN EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE:

The present invention is found to be allowable subject matter as its presentation of a method for directly amplifying a GC rich sequence in the presence of a polyhydric alcohol and ammonium sulfate without any pretreatment steps that lyse the cell, fungus, bacterium or virus in the sample or purify the DNA in any way represents a contribution over the prior art that lacks any such analysis method.

The closest prior art made of record is as follows:

Mercier et al. teach direct PCR from whole blood without DNA extraction using a two-step(hot/cold alternation) incubation that is repeated 3 times before their amplification reaction

and further do not teach the inclusion of a polyhydric alcohol and ammonium sulfate to amplify GC-rich DNA sequences from unlysed cells, fungus, bacterium or virus.(Nucleic Acids Research, Vol. 18, No. 19 1990).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sally A Sakelaris whose telephone number is 571-272-0748. The examiner can normally be reached on M-Fri, 9-6:30 1st Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sally Sakelaris

5/13/2005

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600